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| **Date:** | October 25, 2005 | **Pages:** | (Including cover sheet) | 31 | |
| **Re:** | USSN 09/627,796 – Confirmation No. 3581 | | | | |
| cc: | | cc: | | cc: | |

Please see the attached Petition submitted under 37 C.F.R. §1.181.

BP9806US-CP2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | |
|---|---|---|
| **Application Serial No:** | **09/627,796** | **Confirmation No. 3581** |
| Date Filed: | July 28, 2000 | |
| Application Title: | Non-Nucleic Acid Probes, Probe Sets, Method and Kits Pertaining To The Detection Of Human Chromosomes X, Y, 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 And 20 As Well As 13/21 As A Pair | |
| Applicant: | Krishan L. Taneja | |
| Group Art Unit: | 1634 | |
| Examiner: | Jehanne Souaya Sitton | |
| Action Type: | Reply To The "Decision On Petition" dated August 30, 2005 | |

**Certificate of Transmission:**
**37 C.F.R. § 1.8**

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office (Fax No. 703-872-9306) on this 25th day of October, 2005.

Brian D. Gildea
Reg. No. 39,995

**Attention: Deputy Commissioner For Patents:**

**Petition to the Deputy Commissioner For Patents under 37 C.F.R. § 1.181**
**For Review of the "Decision On Petition" dated August 30, 2005**

Deputy Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

This petition is filed for review of the "Decision on Petition" issued by Jasemine Chambers, Director, Technology Center 1600 on August 30, 2005 (copy attached as Exhibit A). No fee is considered necessary for this petition, but the Office is hereby authorized to deduct any appropriate fee due for the consideration of this Petition to

Deposit Account No. 01-2213 (Order No. BP9806US-CP2). Accordingly, please consider the following petition.

## I. Status of the Application

At the time of the filing of this petition, Applicant filed a response and amendment dated July 26, 2005 in reply to a non-final Office Action dated April 27, 2005. Said amendment is believed to have put the application in condition for allowance, subject only to the "objection" for inclusion of non-elected subject matter resulting from the restriction requirement and related objection discussed below. The Office's communication dated October 17, 2005 appears to be consistent with this understanding. Said Office Action requires Applicant to redact non-elected subject matter else file this petition. (Action dated October 17, 2005 at page 2, paragraph 1).

## II. Petition History

In the above captioned application, the Examiner issued a restriction requirement in Office Action paper No. 9 (Office Action dated September 21, 2001). Applicant did enter traverse of the restriction requirement as well as make appropriate arguments and present a request for reconsideration, in reply to said Office Action, by submission dated January 18, 2002. Applicant did timely file a petition under 37 C.F.R. § 1.144 requesting review of the Examiner's decision by paper dated July 28, 2004 (the "First Petition"). Applicant received a Decision On Petition (the "First Decision") dated April 12, 2005 whereby Applicant's Petition was DENIED.

In response, Applicant filed a petition under 37 C.F.R. § 1.144 or 1.181 (the "Second Petition") on June 10, 2005 requesting reconsideration of the Examiner's decision with regard to a restriction requirement as set forth in Office Action paper No. 9 as well as for review of the First Decision. Responsive to said petition, Applicant received the Decision on Petition dated August 30, 2005 (the "Second Decision"; Exhibit A) wherein Applicant's petition was again DENIED. This paper is being filed for review of said Second Decision.

## III. Preliminary Statement

The Second Decision concludes: "*... at this time no claim is of proper format for allowability in view of the rejections under 35 USC 112 and the objection for encompassing non-elected subject matter...*" (emphasis added; concluding remark of the Second Decision at page 6). It is believed that the rejections under 35 U.S.C. § 112, second paragraph have been addressed by the response and amendment dated July 26, 2005. Regardless, this petition addresses only the restriction requirement and the related "objection" to certain claims as comprising non-elected subject matter.

In the present application, the restriction requirement and related objection at issue attempt to restrict subject matter within a single claim and constitute a refusal to examine subject matter within the scope of that claim. For example, the restriction requirement and associated objection attempt to require applicant to limit the scope of claim 1 to only the elected SEQ ID Nos. 10-16. This is obvious from the present "objection" and the Examiner's withdrawal from consideration all non-elected subject matter (e.g. See: "the Office Action dated April 23, 2003 at paragraphs 1-2, pages 2-3; the Office Action dated January 29, 2004 at paragraph 1, page 2; the Office Action dated April 27, 2005 at paragraph 8, page 5 and the Office Action dated October 17, 2005 at page 2, paragraph 1). Thus, it cannot be disputed that the Office has, by imposition of the restriction requirement and related objection, refused to consider the full scope of Applicant's claims as filed.[1]

In support of the Office's action, the Second Decision reasons:

> "*(a) Applicants correctly point out that the restriction requirement is based upon 35 USC 121.*" (Second Decision at page 1).

and

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1 Unless withdrawn or overruled, the restriction requirement and related "objection" mandates that Applicant must amend single claims to remove non-elected subject matter. There is no avenue whereby the Office will consider the patentability of the claims as filed and pass them to issuance even if there is no basis to "reject" the claim or claims. 37 C.F.R. § 1.142(b) provides: "*(b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.*"

> *"Because no claim in this application has been rejected under 35 U.S.C. 121, the argument that the Office's actions are inconsistent with the holding in In re Weber is not persuasive."* (emphasis added; Second Decision at page 2).

It is respectfully submitted the Office's arguments rest entirely on semantics and indeed they defy the express holding of *In re Weber*, 580 F.2d 455; 198 U.S.P.Q. 328 (CCPA, 1978) and *In re Haas*, 580 F.2d 461; 198 U.S.P.Q. 334 (CCPA, 1978). Specifically, the Second Decision implies that because the Office classifies its actions as an "objection" not a "rejection", *In re Weber* does not apply. However, the situation at hand is precisely the situation that *In re Weber* and *In re Haas* address.[2] In particular, *In re Weber* and *In re Haas* dictate that the Office may not issue a restriction requirement and related objection that require cancellation of subject matter within a single claim regardless of whether or not the single claim includes two of more independent and distinct inventions. Since the Second Petition states: "(c) *Applicants are correct that the Office must follow statute and judicial precedent*" (Second Decision at page 1), it is clear that the restriction requirement and related objection are fatally flawed. Indeed, Applicant takes the view that the present "objection" is a *de facto* "rejection" under 35 U.S.C. § 121.

Applicant further notes that the arguments in the First Decision and Second Decision made in support of the rejection under 35 U.S.C. § 121 appear to only apply to "improper Markush grouping", a situation not asserted in the present restriction requirement. Consequently, any arguments that pertain to "improper Markush grouping" in the restriction requirement, the First Decision or the Second Decision are "irrelevant and off point" in view of the asserted basis for the restriction requirement. For these reasons, reconsideration and withdrawal of the restriction requirement and related objection, the First Decision and the Second Decision are respectfully requested.

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2 *In re Weber* states: ***"As a general proposition, an applicant has a right to have <u>each</u> claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits."*** Underlined text originally in italic, emphasis added in bold, *In re Weber*, 580 F.2d 455, 458, 198 U.S.P.Q. 328, 331, (CCPA, 1978)

**IV. Argument In Support Of Request To Withdraw The Restriction Requirement**

a) The Subject Matter of the Present Controversy is Resolved by *In re Weber*

The Second Decision unequivocally states that the restriction requirement is based upon the Office's authority under 35 U.S.C. § 121. (Second Decision at page 1) *In re Weber* holds that:

> *"It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to Restrict an Application to one of several claimed inventions when those inventions are found to be "independent and distinct". It does not, however, provide a basis to an examiner acting under the authority of the Commissioner to Reject a particular Claim on that same basis."*
>
> ( *In re Weber*, 580 F.2d 455, 458, 198 U.S.P.Q. 328, 331-332 (CCPA, 1978))
>
> ***"We hold that a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses." (emphasis added).***
>
> (*Weber at* 459, 198 U.S.P.Q. at 332 (CCPA, 1978))

Accordingly, it is clear from *In re Weber* that the legal issue of whether or not the Office may impose a restriction requirement and refuse to examine subject matter within the scope of the claim so restricted has been decided against the Office. It is well settled that such requirements violate 35 U.S.C. § 112, where the applicant is statutorily entitled to claim his invention as he deems proper, notwithstanding 35 U.S.C. § 121. **This is true whether or not the single claim comprises two or more independent and distinct inventions.**

The present restriction requirement states: "Restriction to one of the following inventions is required under 35 U.S.C. § 121, and then proceeds to list 13 Groups defined by the same claims (i.e. Claims 1-15, 21-23 and 29-45 – Groups I-V, VII, IX and XI-XVI) and 5 Groups having substantial claim overlap with the previously described 13 Groups (i.e. Groups VI, VIII, X, XVII and XVIII; Office Action dated September 21, 2001 at pages 2-5). Thus, it is clear that the restriction requirement attempts to restrict subject matter within a single claim.

The restriction requirement asserts that these Groups define distinct inventions (paragraph 2 of the September 21, 2001 Office Action at pages 5-6). Consequently, the

Examiner concludes that the restriction requirement is proper under 35 U.S.C. § 121, 37 C.F.R. § 1.142 (a) and 37 C.F.R. § 1.141(a). *Id.* at page 6. Importantly, the rules of practice require Applicant to make an election when responding to the restriction requirement whether or not the restriction requirement is traversed (37 C.F.R. §1.142, 1.143, 1.145 & 1.146), which it was (See: Applicant's response dated January 18, 2002). Consistent with its present actions and its interpretation of the rules of practice, the Office has never considered the patentability of Applicant's claims as filed but has repeatedly imposed an absolute requirement that Applicant redact non-elected subject matter from the claims as originally filed (e.g. See: "Office Action dated April 23, 2003 at paragraphs 1-2, pages 2-3; the Office Action dated January 29, 2004 at paragraph 1, page 2; the Office Action dated April 27, 2005 at paragraph 8, page 5; the concluding remark of the Second Decision (page 6) and the Office Action dated October 17, 2005 at page 2, paragraph 1).

This is precisely the situation that *In re Weber* and *In re Haas* prohibit. That is, even if the Office determines that a single claim defines two or more distinct inventions, it may not issue a restriction requirement as to subject matter within a single claim coupled with an objection that denies consideration of the subject matter of that claim on this basis and thereby *de facto* reject the claim. In the present case the Office characterizes its actions as an "objection", not a "rejection", but its action has the same effect. In essence, whether characterized as an "objection" or a "rejection", both cases ***"violate[s] the basic right of the applicant to claim his invention as he chooses"*** *(In re Weber, 580 F.2d 455, 459, 198 U.S.P.Q. 328, 332, (CCPA, 1978)).* Specifically, the Office refuses to consider the patentability of Applicant's claims as filed and absolutely requires that they be amended to redact non-elected subject matter. Since the actions of the Office are clearly contrary to established precedent, it is respectfully requested that issuance of the restriction requirement and related objection is based upon clear error and accordingly they should be withdrawn.

b) Reliance Upon The M.P.E.P. Cannot Cure Faulty Analysis

The Second Decision acknowledges that: *"Applicants are correct that the Office must follow statute and judicial precedent"*. (Second Decision at page 1) Consequently, nothing in the M.P.E.P. will cure the Office's failure to follow *In re Weber* or *In re Haas*. In particular, references to the M.P.E.P. dealing with cases involving "improper Markush

grouping" are irrelevant and off point. Applicant comments on the arguments in the First Decision and Second Decision as follows:

*(i) M.P.E.P. §803.02*

In the First Decision it was argued, after quoting from M.P.E.P. § 803.02, that: *"The 159 sequences recited in claim 1 of the instant application do not share a common utility nor do they share any substantial structural feature, let alone any substantial feature disclosed as being essential to that utility".* (emphasis added; First Decision at page 3) Later in the First Decision the Office argues:

> *"Applicants' attention is again directed to the MPEP section 803.02 which deals with the treatment of Markush-Type claims which list alternatives having a common core structure and function:*
> *If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions"*
>
> (emphasis added: First Decision at page 4)

The point the Office appears to be making here is that its actions were appropriate based upon a finding that the claims lack "unity of invention" and therefore the claims contain an "improper Markush grouping". However, the Second Decision specifically states that: *"Because no claim in this application has been rejected for containing an improper Markush group, the argument the Office's actions are inconsistent with the holding of In re Harnisch is not persuasive."* (Second Decision at page 2) Consequently, the Second Decision appears to confirm Applicant's belief that Office's reliance on M.P.E.P. § 803.02 in the First Decision is "off point and irrelevant". Importantly, the decision *In re Harnisch* specifically states that:

> *"It should also be clear from what we have said that we adhere to our holdings in In re Weber, supra, and In re Haas (Hass II), supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be reasonably construed to have such an effect"*

(*In re Harnisch*, 631 F.2d 716, 722, 206 U.S.P.Q. 300, 305 (CCPA, 1980)

Consequently, it is clear that the Office's reliance on M.P.E.P. § 803.02 and the decision in *In re Harnisch* will not cure its failure to comply with *In re Weber* and *In re Haas* which decisions specifically prohibit the Office from acting under 35 U.S.C. § 121 to thereby impose a restriction requirement within a single claim coupled with an objection that constitutes a refusal to consider subject matter within that claim. Even under the practice sanctioned in MPEP 803.02, which addresses the possibility of multiple inventions within a single claim, examiners are instructed to first examine the elected invention and if it is determined to be patentable, to continue the search and examination of other subject matter within that claim to determine whether the subject matter in the claim as a whole is patentable. M.P.E.P § 803.02. Thus, apparently the Office has not followed its own protocols in this case.

*(ii) M.P.E.P. § 2175.03(h)*

In the Second Decision the Office argues: "*Applicants also point to In re Harnisch and MPEP 2173.05(h) to argue that the proper test for whether SEQ ID NOs 1-159 are distinct is whether they share a common utility.*" (emphasis added in **bold**, underlined text was originally in *italic*, Second Decision at page 3) It is respectfully submitted that this mischaracterization of Applicant's arguments illustrates another fault with the Office's position. Applicant has argued that it is irrelevant whether or not SEQ ID NOs 1-159 are distinct because *In re Weber* holds that it is improper for the Office to restrict one or more inventions within a single claim and refuse consideration of subject matter within the scope of that claim to determine whether it is patentable regardless of whether or not they are "independent and distinct". The argument set forth in the Second Decision clearly being based upon an incorrect premise renders its related arguments and conclusion to be "irrelevant".

*(iii) M.P.E.P. § 808*

At page 5 of the Second Decision it has been argued:

*"MPEP 808 sets forth further guidance for insisting upon restriction:*

> *Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why the inventions as claimed are either independent or distinct; and (B) the reasons for insisting upon restriction there between as set forth in the following sections.*

*The arguments appear to be directed to the elected invention, probes comprising SEQ ID NOs 10-16. These arguments are not commensurate with the invention as claimed. MPEP 808 explains that it is the invention, as claimed, which is considered for distinctness and independence."*

(Second Decision at page 5)

It is clear from the forgoing that again the Office's arguments pertaining to M.P.E.P. § 808 focus on determining when an invention is independent or distinct. However, since the present restriction requirement attempts to apply a restriction within a single claim under 35 U.S.C. § 121 and deny consideration of subject matter within the scope of that claim, this analysis is again "off point and irrelevant". This is clear since *In re Weber* and *In re Haas* specifically hold that the Office may not restrict within a single claim under 35 U.S.C. 121 and deny consideration of subject matter within the scope of that claim regardless of whether or not it claims two or more inventions that are "independent and distinct". *(In re Weber, 580 F.2d 455, 458, 198 U.S.P.Q. 328, 332, (CCPA, 1978))*

*(iv) M.P.E.P. § 803.04*

At page 6 of the Second Decision, it is stated that:

*"MPEP 803.04 explains how claims directed to polynucleotide sequences claimed both individually and in sets will be restricted and examined."*

(Second Decision at page 6)

The Second Decision then goes on to explain how the Office supposedly applied M.P.E.P. § 803.04 to the present claims based upon the presumption that restriction is proper.[3] However, it is self-evident that *In re Weber* and *In re Haas* prohibit the Office from restricting, for example, SEQ ID NOs. 1-159 within claim 1 under 35 U.S.C. § 121 coupled with an objection that denies consideration of subject matter within the scope of claim 1. Consequently, this argument is again "irrelevant and off point" since no such presumption is valid.

*(v) Summary*

In summary, it is clear that like the First Decision before it, the Second Decision confuses the concepts of misjoinder of invention under 35 U.S.C. § 121 with the related but distinct concept of "improper Markush grouping". Moreover, both the First Decision and the Second Decision are based upon an incorrect presumption that it is permissible for the Office to restrict within a single claim under 35 U.S.C. § 121 and thereby deny consideration of subject matter within the scope of that claim. Because conclusions that are based upon incorrect premises are inherently flawed, it is clear that the Office's improper reliance on this incorrect premise and the M.P.E.P. cannot cure the faulty analysis of the First Decision and the Second Decision. Accordingly, reconsideration and withdrawal of the Restriction Requirement and related objection are respectfully requested.

c) Applicant Reiterates That "Unity of Invention" Exists

In support of the First Decision and the Second Decision, the Office repeatedly has quoted from the M.P.E.P., which itself often makes reference to *In re Harnisch*, 631 F.2d 716, 206 U.S.P.Q. 300 (CCPA, 1980) and *Ex Parte Hosumi*, 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984), with an emphasis on attempting to show that there is no common

3 Since M.P.E.P. § 803.04 appears to absolutely require that single claims comprising 10 or more different nucleotide sequences be restricted, the section is clearly in conflict with *In re Weber* and *In re Haas*. Since the Office has acknowledged that they must comply with binding precedent (Second Decision at page 1), reliance on this section of the M.P.E.P. is clearly improper.

utility[4] to the 159 different PNA probes claimed in, for example, claim 1. For example, the Second Decision argued:

> *"As explained in the previous decision, the 159 peptide nucleic acid sequences recited in claim 1 of the instant application do not appear to share a common utility nor do they share any substantial structural feature, let alone any substantial feature disclosed as being essential to that utility. Probes which bind to common structure, such as a selected chromosome, are not required to share a common structure. This is supported by the comparisons of SEQ ID Nos 10-16, which appear to share no significant structure in common and yet hybridize to Chromosome Y. This is because the probes hybridize to different regions of Chromosome Y. This is the case in the instant application and the Office has grouped the probes based on their specific chromosome binding affinity (i.e. binding to chromosomes X, Y, 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 or 20, etc...) and thus every invention has been placed within a group which has a common utility.*
>
> *MPEP 2175.03(h) states in part that:..."*
>
> (Second Decision at page 4, emphasis added)

As previously discussed, that line of reasoning is irrelevant and off point since the restriction requirement is based upon misjoinder of invention under 35 U.S.C. § 121 and not based "improper Markush grouping". Regardless, Applicants disagree with the analysis and conclusion. Specifically that there is no common utility to the 159 peptide nucleic acid probes claimed in, for example, claim 1 or that, by implication, there is no "unity of invention" thereby leading to the conclusion that an improper Markush group has been claimed by Applicant.

*In re Harnisch* dealt with a Markush claim (and related dependent claims) to "coumarin compounds" that were admittedly all "dye stuffs"[5]. Thus, all the "coumarin compounds" had an asserted common utility that was identified in the specification. In

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4 In *Harnisch* the court discussed the use of "a single structural similarity" as being the appropriate test since *"in any Markush group the compounds "will differ from each other is certain respects"* and the court used the *"unity of invention""* criteria to establish whether or not *"unrelated inventions are involved"*. *In re Harnisch*, 631 F.2d 716, 722, 206 U.S.P.Q.2d 300, 305-306 (CCPA, 1980)

5 The *Harnisch* court seemed to rely heavily on the admission of the solicitor in its opinion. See: *In re Harnisch*, 631 F.2d 716, 719, 206 U.S.P.Q. 300, 303 (CCPA, 1980)

*Harnisch*, the examiner had rejected the claims under 35 U.S.C. § 121 but the Board of Patent Appeals and Interferences (BPAI) summarily reversed that rejection citing to *In re Weber* and *In re Haas*. *In re Harnisch* at 717, 206 U.S.P.Q at 301. However, the BPAI rejected the claims as being "drawn to improper Markush groups". *Id.* at 717-718, 206 U.S.P.Q. at 301. The BPAI reasoned:

> *"Applying the facts of this case to the principles enumerated, we find that the members of the Markush groups of the claims do not belong to a known or recognized genus and possess widely different physical or chemical properties. Aside from the obvious fact that the compounds encompassed by the claims are not functionally equivalent, said compounds, considered as a whole, are so dissimilar and unrelated chemically or physically that it would be repugnant to accepted principles of scientific classification to associate them together as a generic group. For example, the types of derivatives encompassed by the Markush claim may include polyfused N-heterocyclics, cyclic, acyclic and aromatic amines, sulfonamides, phthalimides, quarternary ammonium salts, phosphorus heterocyclics, phosphates, aldehydes, azomethines, hydrazones, ethers, esters, halogens, alcohols, nitriles, piperidines, furanes, pyrroles, indoles, amongst others. It is clear on the record the involved compounds cannot be considered functionally equivalent, in fact some being no more than intermediates for the others. ... The mere fact that there is a single structural similarity (i.e., the coumarin group) in not in itself sufficient reason to render all the embodiments functionally equivalent, particularly when the ultimate properties of the final products would not be expected to possess any recognized functional relationship."*
>
> (*Id.* at 718, 206 U.S.P.Q. at 302, emphasis added in bold, underlined text in *italic* in the original)

Notwithstanding this characterization of the claims, the court in *Harnisch* found that the BPAI had erred for not recognizing that all of appellant's claimed compounds were dye stuffs (i.e. the common function) having a "single structural similarity" (i.e. the coumarin group), therefore possessed a "common utility" and thereby possessed "unity of invention". *Id.* at 722, 206 U.S.P.Q. at 305.

As argued by Applicant in the Second Petition, in determining what constitutes "common utility", *In re Harnisch* expressly states:

> *"Over thirty years ago this court decided In re Jones, 34 CCPA 1150, 162 F.2d 479, 74 USPQ 149 (1947), reversing an "improper Markush group" rejection of*

*claims to chemical compounds which were [*722] growth-regulating compositions for plants, fungicides, and insecticides.* ***Notwithstanding their various properties, the court found all of the compounds included in the claims were plant growth stimulants, thus having a common function.*** *The court noted that in any Markush group the compounds "will differ from each other in certain respects." It laid down the proposition, with which the PTO agrees in its M.P.E.P., that* ***in determining he propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components."*** *(emphasis added)*

(*In re Harnisch*, 631 F.2d 716, 722, 206 U.S.P.Q. 300, 305 (CCPA, 1980)

From the foregoing it is clear that The Office should not, when considering the appropriateness of Markush groupings, **focus on trivial distinctions of elements, or other components, of the claimed compounds but must consider the compounds, and their associated functions, as a whole.**

This position seems to also be supported by M.P.E.P. § 2173.05(h), which reads:

*"The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound),* ***it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly reasonable for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property."*** *(emphasis added)*

(M.P.E.P. § 2173.05(h)

In the present case, the Examiner, as well as the First Decision and the Second Decision, focuses on trivial distinctions associated with elements, or other components, of PNA (i.e. the nucleobases) and not on the compounds and their associated common property and common function as described in the specification, when considered as a whole. That is the nature of the asserted error.

For example, the Second Decision reasons:

*"As set forth in the previous decision, with respect to the nature of the invention, the claimed probes are not traditional nucleic acids, they are PNA or*

*Peptide-Nucleic acids and have been claimed as "Non nucleic acid probes."[6] The difference with a PNA is that the backbone is not a traditional sugar-phosphate nucleic acid backbone, but one that has peptide structures. PNA's function like nucleic acids in that they contain a sequence of bases (usually traditional nucleotide bases) (what is termed in the claims as a probing nucleobase sequence) which is responsible for the hybridization of a PNA to DNA.[7]*

(Footnotes added; Second Decision at page 3)

Thus, the Second Decision continues, like the First Decision, to focus on nature of the nucleobases linked to the peptide nucleic acid backbone and therefore fails to consider how these various claimed PNA probes are related with respect to their common property and common function in the context of the specification when viewed as a whole. In particular, the restriction requirement, the First Decision, the Second Decision all fail to recognize that the 159 different PNA probes are all PNA probes (i.e. common property or single structural similarity) and all hybridize to human chromosomes (i.e. the common function) and thereby can be used, alone or in combination, to determine human chromosomes and/or distinguish between different human chromosomes. For example the specification reads:

*"The non-nucleic acid probes of this invention are suitable for detecting, identifying or quantitating human chromosomes X, Y, 1, 2, 3, 4, 6, 7.8, 9, 10, 11, 12, 16, 17, 18 or 20, as well as 13/21 as a pair, in a sample or in the individual cells of the sample."*

(Specification at page 21, lines 2-5)

That common utility was also demonstrated in specification by the Examples and illustrated in the Figures. For Example, Figures 12A and 12B illustrate the simultaneous determination of chromosomes X, Y and 1 using a mixture of the claimed PNA probes. All other of the 159 PNA sequences were likewise shown to be suitable for the analysis

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6 All claims have now been limited to peptide nucleic acid probes so this distinction is no longer relevant.

7 This statement alone is recognition by the Office that peptide nucleic acids represent an art recognized class of molecules (i.e. have a common property recognized by the art).

of human chromosomes (c.f. Example 9 of the specification and the related Figures). It is self-evident that the 159 PNA probes can be mixed in other ways to perform similar assays for the determination of the same and/or other chromosomes[8], such as for example their use in a prenatal assay (Specification at page 11, lines 9-17). Thus, in the present application, it is clear that all of the PNA probes are PNA probes (i.e. common property) and all of SEQ ID Nos. 1-159 can be used for determining "human chromosomes" (i.e. common function).

Interestingly, the Second Decision asserts that a PNA probe of SEQ ID No: 10 could not be substituted for a PNA probe of SEQ ID No. 9 because the PNA probe of SEQ ID No: 10 will hybridize to human chromosome Y while SEQ ID No. 9 will hybridize to human chromosome X. (Second Decision at page 4) While true, this distinction is off point.

In *Harnisch* the BPAI attempted to distinguish between compounds that were "dye stuffs" (a common function) and compounds that were intermediates to "dye stuffs" thereby suggesting that this distinction was a critical difference. *In re Harnisch* at 717-718, 206 U.S.P.Q. 300 at 301-302. In *Harnisch*, it was determined that all of the "coumarin compounds" (common property) were dye stuffs (common function); albeit true that some were intermediates (a subgenus) to other coumarin compounds. Thus, the BPAI's focus on an asserted subgenus was its error.

In the present case, by focusing on various disclosed subgenera (i.e. groups of PNA probes for various individual chromosomes) and not on the genus disclosed in the specification (i.e. PNA probes for the analysis of some or all human chromosomes), the Office makes an error that is remarkably similar to that found in *Harnisch*. In particular, the restriction requirement, the First Decision and the Second Decision focus on trivial

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8 The specification expressly states: "*In preferred embodiments, non-nucleic acid probes are organized into a set that is designed to detect, identify or quantitate, individually or together with other chromosomes, each of chromosomes X, Y, 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18 and/or 20, as well as 13/21 as a pair, that may be present in the sample. In a most preferred embodiment, a probe set is suitable for the specific detection, identification and/or quantitation of the total number of each of human chromosomes X, Y, 1, 2, 3, 4,6, 7, 8, 9, 10, 11, 12, 16, 17, 18 and/or 20, as well as 13/21 as a pair, in a sample of interest. Preferably, the probes or probe sets are integrated into an assay used for the simultaneous detection, identification and/or quantitation of some or all human chromosomes.*" (emphasis added)

distinctions associated with the nucleobases linked to the PNA probes. The Office's attempt to classify (or group) the probes at the subgenus level (i.e. one group of PNA probes for chromosome X, one group of PNA probes for chromosome Y, etc) is arbitrary and ignores the specific teachings of the specification. These analyses are flawed because they fail to recognize that PNA probes comprises a common backbone structure (i.e. a single "structural similarity", *In re Harnisch* at 722, 206 U.S.P.Q. 300 at 305) to which differing nucleobases are linked such that all of the PNA probes claimed, for example in claim 1, relate to the common utility (i.e. the genus) as disclosed in the specification. Specifically, that these 159 different PNA probes can all be used to analyze human chromosomes (i.e. the genus) as opposed to rat chromosomes or bird chromosomes or reptile chromosomes. Thus, Applicant has clearly claimed many related PNA probe compounds that make up a proper Markush group as did the many "coumarin compounds" of *Harnisch*. *In re Harnisch* at 722, 206 U.S.P.Q. 300 at 305-306. Consequently, Applicant reiterates that "unity of invention" exists within the 159 PNA probes claimed, for example, in claim 1.

d) Summary

It is respectfully submitted that based upon the foregoing arguments, it is self-evident that the restriction requirement and related objection set forth in the Office Action dated September 21, 2001 is flawed. Specifically, the restriction requirement and related objection conflict with the express holding of *In re Weber* and *In re Haas*. Although it is acknowledged that the Office classifies its present action as an "objection" and not a "rejection" of the claims, it is equally clear that this is a distinction without a difference. Specifically, in both cases Applicant is required by the rules of practice to amend the claims to redact non-elected subject matter within a single claim so that said claims have never, and will never be, examined on their merits as filed. Thus, the Office's actions are clearly inconsistent with *In re Weber* and *In re Haas* and thereby constitute a *de facto* "rejection". Applicant further submits that the claims use proper Markush grouping but that, in any event, this is immaterial given the basis for the restriction requirement and related objection. Since the Office must follow statute and judicial precedent, the present "objection" is clear error. Withdrawal of the restriction requirement and related "objection" to claims is therefore respectfully requested.

Respectfully submitted
On behalf of Applicant,

Oct 25, 2005

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